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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
OAKLAND DIVISION

LISA ROSILLO and JESSE KOHN,  
individually, and on behalf of those  
similarly situated,

Plaintiffs,

v.

ANNIE'S HOMEGROWN, INC. and  
GENERAL MILLS, INC.,

Defendants.

Case No. 4:17-cv-02474-JSW

**JOINT STATUS REPORT RE: STAY**

1 Pursuant to the Court's January 26, 2018, Order Continuing Stay and Requiring Joint  
2 Status Report (ECF No. 50), Plaintiffs Lisa Rosillo and Jesse Kohn ("Plaintiffs") and Defendants  
3 Annie's Homegrown, Inc. and General Mills, Inc. ("Defendants") submit this Joint Status Report  
4 to advise the Court of their respective positions on whether the stay currently in place in this  
5 matter should continue.<sup>1</sup> Each party's position is set forth below.

#### 6 PLAINTIFF'S POSITION

7 There has been no indication whatsoever since the Court's last Order that any rulemaking  
8 is forthcoming. This case has been on file since May 1, 2017. The Court and the parties cannot  
9 wait indefinitely. *See, e.g.*, 1/26/18 Order (stating that the Court "will not indefinitely stay this  
10 case on the hope that Congress or the FDA will eventually, at some unknown point in time, have  
11 something to say on this issue. In July 2018 . . . over two years will have elapsed since the  
12 comment period closed. The Court will be disinclined to continue the stay beyond July 2018  
13 unless the FDA has made some indication that the regulatory process is close to completion."").  
14 Because the FDA has not indicated that the regulatory process is close to completion, Plaintiffs  
15 respectfully request that the Court lift the stay currently in place.

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27 <sup>1</sup> A related case, *Campbell v. Annie's Homegrown, Inc.* (Case No. 17-cv-07288-JSW) is currently  
28 pending before this Court. The *Campbell* matter is stayed on the same basis as this action.

## DEFENDANTS' POSITION

In the past year, the Commissioner of the U.S. Food and Drug Administration ("FDA") has on three separate instances confirmed that the agency is actively exploring regulation of "natural" claims on food products, assuring the public most recently that the agency "will have more to say on the issue soon." In light of the Commissioner's recent assurances that the FDA has not tabled regulation of "natural" claims, but rather has made it a top agency priority which nears completion, Defendants respectfully request that the Court continue to stay this action in deference to the FDA's regulatory process.

### A. FDA Action on Regulation of "Natural" Claims

When the FDA's comment period concerning use of "natural" claims on food labeling closed on May 10, 2016, the agency faced review of 7,690, comments, during the midst of which a change in administration and leadership within the agency would take place. While during the months following closure of the comment period the FDA did not offer public statements about the work it was performing, the agency's Commissioner, Dr. Scott Gottlieb, has in recent months repeatedly assured the public that regulation of "natural" is a priority at the FDA and that the agency will speak to the issue "soon."

The FDA's assurances have been unambiguous: the Agency is working to address "natural" claims, and the regulatory process is now in its final stages. First, in October, 2017, Commissioner Gottlieb confirmed "[the FDA] is looking at how to define 'healthy' and 'natural' more uniformly."<sup>2</sup> Then, in February of this year, the Commissioner acknowledged in an emailed statement to the New York times that "[w]e recognize that consumers are trusting in products labeled 'natural' without clarity around the term," and further assured the public that "Consumers have called upon the F.D.A. to help define the term 'natural' and we take the responsibility to provide this clarity seriously. We will have more to say on the issue soon."<sup>3</sup>

<sup>2</sup> Heather Haddon, FDA Commissioner Wants Closer Look at Health Claims on Packaging, Wall Street Journal (Oct. 10, 2017), <https://www.wsj.com/articles/fda-commissioner-wants-closer-look-at-health-claims-on-packaging-1507673335>.

<sup>3</sup> Julie Creswell, Is it 'Natural'? Consumers, and Lawyers, Want to Know, The New York Times (Feb. 16, 2018), <https://www.nytimes.com/2018/02/16/business/natural-food-products.html>

1 And most recently, in March 2018, Commissioner Gottlieb highlighted the Agency's work  
 2 on "natural" claims during his keynote address at the National Food Policy Conference.<sup>4</sup> The  
 3 Commissioner's full remarks are as follows:

4 In late 2015, we sought feedback from consumers and the industry on whether  
 5 FDA should define and regulate the word "natural" on food labeling. More than  
 6 7,600 comments came in, and we've reviewed them. It's clear that consumers  
 7 increasingly want to know what is in the food they eat and whether it is "natural."

8 We recognize that consumers are trusting in products labeled as "natural" without  
 9 clarity around the term.

10 Just like other claims made on products regulated by FDA, we believe the  
 11 "natural" claim must be true and based in science.

12 At the same time, we know that there are wide differences in beliefs regarding  
 13 what criteria should apply for products termed "natural" -- and some of those  
 14 criteria aren't based on public health concerns.

15 We'll have more to say on the issue soon.<sup>5</sup>

16 These remarks, coupled with consistent messaging from the Agency over the past year, confirm  
 17 regulation of "natural" is not shelved indefinitely at the FDA. To the contrary, the FDA  
 18 recognizes the immense public interest in use of this term on food labeling, and is poised to act  
 19 "soon."

#### 20 **B. The Court Should Continue to Stay This Action in Deference to the FDA**

21 Primary jurisdiction doctrine compels that if a plaintiff's claim implicates technical and  
 22 policy questions that should be addressed in the first instance by an agency with regulatory  
 23 authority over the relevant industry, the judicial branch should stand down. *Clark v. Time Warner*  
 24 *Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). This Court has already concluded that all of the  
 25 elements that compel application of primary jurisdiction apply to this case and favor that it be  
 26 stayed pending FDA guidance regarding "natural" claims. *See* Order Staying Case and Denying  
 27 Motion to Dismiss Without Prejudice (Oct. 17, 2017) (ECF No. 46) ("Stay Order") at 3-6. Indeed,  
 28 the only real question that has been put to the Court over the past year is not whether this case

<sup>4</sup> Remarks by Scott Gottlieb, M.D., National Food Policy Conference, Washington, DC (Mar. 29, 2018), available at <https://www.fda.gov/NewsEvents/Speeches/ucm603057.htm>

<sup>5</sup> *Id.*

1 should be stayed, but for how long. While Defendants can appreciate the Court's hesitance to  
2 impose an indefinite stay (and do not ask the Court to do so), there are salient reasons to continue  
3 the stay for the time being in light of the FDA's recent public assurances that "natural" claims  
4 will be addressed soon.

5 First and foremost, there can no longer be any real dispute that the FDA is, in fact, doing  
6 its due diligence to review the thousands of comments regarding "natural" it received and  
7 synthesize those comments into a cohesive national policy, or, at minimum, an Agency response.  
8 Indeed, the Agency's head has in March of this year confirmed its review of public comments is  
9 complete and that the Agency will speak to natural claims "soon." *See* Note 4, *supra*. In the midst  
10 of this activity and imminent FDA action, there is no cogent reason to begin litigation now over  
11 the precise issue the FDA is poised to address.

12 Moreover, there is no question that this case, and the hundreds of other "natural" cases  
13 pending on the federal docket, will benefit from the uniformity that federal FDA guidance will  
14 offer. As this Court recognized in its prior Stay Order, "[a]waiting guidance from the FDA on the  
15 use of the term 'natural' on food labels will help ensure that there are not conflicting judicial  
16 rulings, indirectly resulting in a patchwork of disclosure requirements which would require  
17 manufacturers to print different labels for different states." Stay Order at 6. Put differently,  
18 Agency guidance is especially necessary here because "there are wide differences in beliefs  
19 regarding what criteria should apply for products termed 'natural' -- and some of those criteria  
20 aren't based on public health concerns." *See* Note 4, *supra*.

21 For these reasons, Defendants request that the Court continue to stay this action in  
22 deference to the FDA. Defendants recognize the Court's direction that it would be "disinclined to  
23 continue the stay beyond July 2018 unless the FDA has made some indication that the regulatory  
24 process is close to completion," but now the FDA has done just that. *See* Order Continuing Stay  
25 and Requiring Joint Status Report (January 26, 2018) (ECF No. 50) at 1; Section A, *supra*.

1 DATED: July 27, 2018

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13 DATED: July 27, 2018

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23 *Counsel for Plaintiffs Lisa Rosillo and Jesse  
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24 **ATTESTATION**

25 Pursuant to Civil Local Rule 5-1(i)(3), I hereby attest that all signatories to this document  
26 concur in its filing.

27 Dated: July 27, 2018

/s/ Mica D. Simpson